

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

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| IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD- 02327, MDL No. 2187 |
| THIS DOCUMENT RELATES TO: <i>Ethicon Wave 12 cases listed as Exhibit A to Ethicon's Motion</i> | JOSEPH R. GOODWIN U.S. DISTRICT JUDGE |

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS'
MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS
OF NIAL GALLOWAY, M.D., FOR WAVE 12**

Plaintiffs respectfully request that this Court deny Defendants Motion to Exclude Certain General Opinions of Niall Galloway, M.D., for Wave 12.

INTRODUCTION

Niall Galloway is a urologist based in Atlanta, Georgia, at the Emory School of Medicine. He has a medical degree from the University of Aberdeen in Scotland. He was awarded the Fellowship of the Royal College of Surgeons of England in 1979, and the Fellowship of the Royal College of Surgeons in Edinburgh in 1980. (Galloway Acosta Report, Ex. 2 to Def. Mot., Dkt. No. 8789-2, at p. 1). In practice, he initiated collaboration between the Urology and Gynecology specialties, leading to the first multidiscipline Continence Clinic in Scotland. (*Id.*).

After moving to the United States, he was elected to the Atlanta Urological Association in 1990 and in 1992, and he co-founded the Emory Continence Center, where he presently serves as the medical director. (*Id.* at 1-2). He has authored numerous book chapters, abstracts, and peer-reviewed journal articles, and he has given presentations regarding pelvic floor disorders,

including pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). (*Id.* at 2). In his surgical practice, Dr. Galloway has extensive experience in dealing with complications related to placement of synthetic mesh in the vagina to treat POP and SUI. (*Id.*). He has been designated to offer general and case-specific opinions for two cases in Wave 12.

This Court should deny Ethicon’s motion and allow him to opine about degradation—which is central to any opinions about the effects of the mesh on the human body—and should allow him to opine that mesh has caused a public health crisis, because it has. Ethicon also moves to exclude legal opinions, and Plaintiffs agree that the expert should not testify as to legal conclusions. What is, or is not, a legal conclusion should be determined by the trial-court judge within the necessary context at trial.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents “scientific knowledge,” meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert’s opinions “fit” the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

LEGAL ARGUMENT

I. As this Court has held on numerous occasions, Dr. Galloway is well qualified to opine about degradation and other properties of Ethicon's mesh.

Ethicon's first argument goes only to Dr. Galloway's qualifications. As noted above, there are numerous ways in which an expert may be qualified under Rule 702: by "knowledge, skill, experience, training, or education." This Court should reject Ethicon's argument that Dr. Galloway does not have the necessary qualifications to opine about degradation of the mesh. He is qualified at least by knowledge and experience, as this Court has recognized multiple times.

This Court should have little trouble denying this aspect of Ethicon's motion, as the Court has already addressed this exact argument. Plaintiffs recognize that some issues may vary from case to case, as the facts change. However, on an issue of qualifications, there is no logical reason to hold an expert to be unqualified if he has already been held to be qualified. Addressing this exact issue in a prior case, this Court wrote:

First, BSC argues that Dr. Galloway is not qualified to opine on biomaterials and that his opinions are unreliable. With regard to his qualifications, BSC points to Dr. Galloway's deposition testimony where he states that he is not an expert in biomaterials. BSC's Mot. re: Galloway 5 [ECF No. 32]. However, this testimony is not dispositive. *See Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *36 (S.D. W. Va. July 8, 2014) (finding Dr. Johnson qualified to opine about polypropylene notwithstanding his deposition testimony). I have previously found certain medical doctors qualified to opine as to polypropylene. *See* Mem. Op. & Order 6–9, *Jones v. Bard, Inc.*, No. 2:11-cv-00114 [ECF No. 391] (finding Dr. Ostergard qualified to opine as to polypropylene and product design); *see also Huskey*, 2014 WL 3362264, at *35–37 (finding Dr. Johnson qualified to opine as to mesh degradation).

Like the physicians in these prior cases, Dr. Galloway is an accomplished urologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. *See* Pl.'s Resp. re: Galloway 6–7 [ECF No. 75] ("His opinions are founded on a deep understanding of anatomical processes as they related to permanent surgical implants, along with his clinical observations from performing hundreds of revision and removal procedures involving mesh."). Dr. Galloway's clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction.

Accordingly, BSC's motion with regard to Dr. Galloway's qualifications is **DENIED**.

Trevino v. Bos. Sci. Corp., No. 2:13-CV-01617, 2016 WL 2939521, at *5 (S.D.W. Va. May 19, 2016).

This Court has also rejected the specific argument that Ethicon makes in its motion. Ethicon argues that Dr. Galloway admitted in his deposition that he is not a biomaterials expert or a pathologist. (Def. Mot. at p. 3). However, this Court has recognized that such statements are not dispositive as to an expert's qualifications to give an opinion:

BSC argues Dr. Galloway is unqualified because he stated he is not an expert in biomaterials at his deposition. This testimony, however, is not dispositive. Dr. Galloway is an accomplished urologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Dr. Galloway's clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction. Accordingly, BSC's motion with regard to Dr. Galloway's qualifications is **DENIED**.

Robbins v. Boston Sci. Corp., No. 2:12-CV-01413, 2016 WL 3189248, at *12 (S.D. W. Va. June 7, 2016).

Dr. Galloway's report contains a section titled: "Degradation, chronic inflammation, and possible toxicity create unknown long-term effects in a woman's vagina." (Galloway Acosta Report, Dkt. No. 9789-2, at pp. 6-8). As seen in the report, Dr. Galloway's opinions are based on his extensive study of the scientific literature. (*Id.*). His report further discusses degradation, as seen in the scientific literature, in the context of other problems associated with Ethicon's polypropylene mesh. (*See id.* at pp. 4 n.5, 6 n.11, 11-12 n.27). His opinions are also informed by years of work as a pelvic-floor surgeon addressing these exact issues. (*Id.* at p. 2). As stated in his report:

The opinions expressed in this report are based on my experience treating women with mesh complications and surgically removing mesh and the medical and scientific literature. All my opinions have been made to a reasonable degree of medical certainty.

(*Id.*). Based on his literature review and his practice, Dr. Galloway is qualified by experience and knowledge to opine about the properties of the mesh, as this Court has ruled in several prior cases. *See Trevino*, 2016 WL 2939521, at *5; *Robbins*, 2016 WL 3189248, at *12; *see also Holcomb v. Bos. Sci. Corp.*, No. 2:12-CV-06302, 2016 WL 3189787, at *11 (S.D. W. Va. June 7, 2016); *Franco v. Bos. Sci. Corp.*, No. 2:12-CV-02748, 2016 WL 3248505, at *11 (S.D. W. Va. June 13, 2016); *Hackney v. Bos. Sci. Corp.*, No. 2:12-CV-05248, 2016 WL 3189252, at *11 (S.D. W. Va. June 7, 2016); *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *5 (S.D. W. Va. Apr. 24, 2015).

Dr. Galloway has not lost the qualifications that the Court has determined that he has, on many occasions. Therefore, Ethicon's motion on this point should be denied.

II. Dr. Galloway's opinion that Ethicon has created a "public health crisis," and that there is a field of medicine devoted to fixing the problems caused by mesh, are relevant and not unfairly prejudicial. These opinions are based on what Dr. Galloway has seen in his own practice and the scientific literature.

Ethicon next challenges Dr. Galloway's opinion that Ethicon's mesh has caused a "public health crisis." (*See Galloway Acosta Report*, Dkt. No. 8789-2, at p. 2). Ethicon also challenges Dr. Galloway's statement that "I am not aware of any other surgical procedure that has created as 'new disease' such as what we are seeing since the introduction of trans-vaginal mesh. It has been given a name in the recent literature, 'Meshology.'" (*Id.* at 21-22). The remainder of the report provides support for that opinion, by explaining how Ethicon's mesh products have harmed numerous women, as Dr. Galloway has seen in his own practice. In addition, the "Meshology" quotation cites directly to an article with that title. (*See id.* at 22 n.54, citing Lee et al., *Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes*, *Expert Rev. Med. Devices* Early online, 1-16 (2014)).

The rules at issue are Federal Rules of Procedure 401 and 403. Rule 401 holds evidence to be relevant if it has “any tendency to make a fact more or less probable than it would be without the evidence.” Here, Dr. Galloway’s report notes that the scientific literature has recognized that mesh injuries are so prevalent that a new field has been developed to address those complications. This fact is relevant to the question of whether Ethicon’s mesh products are harmful—which is the nut of the general causation inquiry.

Rule 403 asks whether the probative value of the evidence at issue “is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. Two aspects of the rule are key: The dangers of the evidence must “substantially” outweigh the evidence’s probative value, and the risk of prejudice must be “unfair.” Ethicon argues that these statements are unfairly prejudicial, but it is not “unfair” to recognize what Ethicon’s products have done. They **have** created a public health crisis, as Dr. Galloway has seen in his own practice and in the literature. (*See generally*, Galloway Acosta Report, Dkt. No. 8789-2). And, **there is** a developing field of medicine designed to treat these problems, as seen in the scientific literature. (*See id.* at p. 22, n.54).

For these reasons, this Court should permit Dr. Galloway to give the challenged opinions.

III. Any issues regarding legal conclusions should be addressed at trial.

Plaintiffs acknowledge that this Court has consistently held that experts may not offer legal conclusions as part of their testimony. However, Defendants go too far in trying to prevent Dr. Galloway from opining that Ethicon’s devices are “flawed.” This Court should hold that these issues should be addressed with objections in the context of trial.

The Fourth Circuit rule on legal conclusions is stated as follows: “We identify improper legal conclusions by determining whether “the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.” *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). For instance, “unreasonably dangerous” would probably qualify as a legal conclusion under that standard, but “flawed” clearly would not. Rather than parse out Dr. Galloway’s report, this Court should issue a general prohibition on legal conclusions and let the trial judge sort out what is, or is not, a legal conclusion based on objections at the time of trial.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that Ethicon’s motion to exclude aspects of Dr. Galloway’s testimony be denied.

Dated: November 18, 2019

Respectfully submitted,

/s/ D. Renee Baggett

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CERTIFICATE OF SERVICE

I hereby certify that on the 18th day of November, 2019, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service.

/s/ D. Renee Baggett _____
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